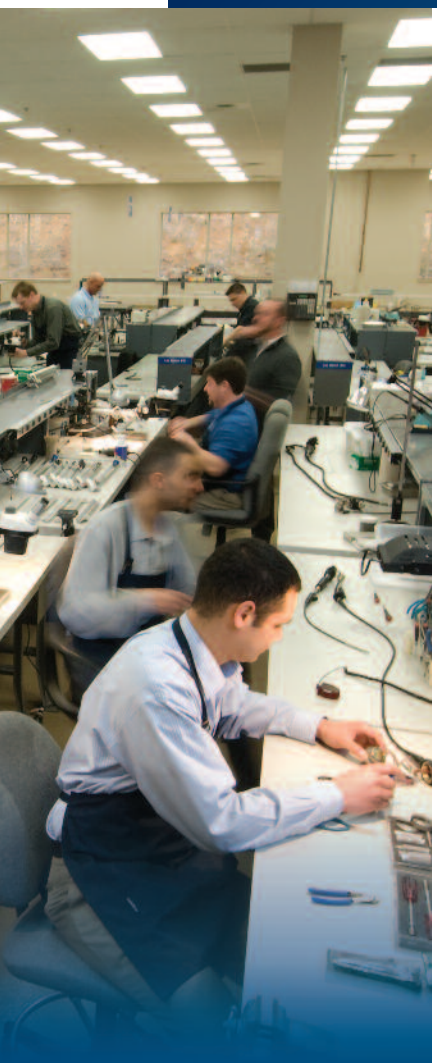
What is ISO 13485?



The ISO medical device standard (ISO 13485) represents an international consensus on outstanding management practices of ensuring consistent and exacting quality requirements. Although similar to ISO 9001/9002, IS0 13485 is specific to the repair of medical devices, and therefore a more relevant certification for our business.

Total Scope, Inc. is certified to the ISO 13485 quality standard and has been since 2001, through a rigorous audit process comparable to Joint Commission Audits.

Total Scope, Inc. was the FIRST scope repair company in the US with ISO 13485 certification.

ISO 13485:2003
FM 74758

How does ISO 13485 directly affect repair and service quality?

- Total Scope, Inc. must be positive it can meet all customer requirements prior to accepting an order.
- All parts and suppliers undergo an annual review to ensure all parts are equal to or superior to the manufacturer.
- Master device records containing device specifications and process requirements are established and maintained for each medical device.
- Repairs are closely monitored to verify conformance to set procedures.
- Scopes are inspected several times before their departures.
- Environmental conditions are controlled and monitored as they affect product quality.
- Verified and authorized batch records must be maintained.
- Device history is kept on all medical devices, which includes a lot numbering system for recall purposes.
- Satisfaction levels are monitored and addressed through customer feedback surveys.

Which company will you entrust with your scope?

Total Scope, Inc.
The Leader in Medical Device Repair

17 Creek Parkway, Upper Chichester, PA 19061 • 800-471-2255 • Fax: 484-490-2150 • www.totalscopeinc.com